SEVERE ADVERSE EVENT (SAE) REPORT FORM

STUDY TITLE			
PROTOCOL NO.		SITE NO.	
SITE			
PATIENT ID		DATE OF REPORT	

1.	SAE Date of Onset:		
2.	SAE Date Stopped:		
3.	Location of SAE:		
4.	Was this an unexpected adverse event?		☐ Yes ☐ No
5.	Brief description of participants (do not include personal identifiers):	Gender	☐ Male ☐ Female ☐ Other, identify
		Age	
		Diagnosis for study participation	
6.	Brief description of the nature of the SAE: *attach description, if applicable*		
7.	Category of SAE:	☐ Date of Death: ☐ Life threatening ☐ Congenital anomaly, birth defects ☐ Life threatening ☐ Required intervention to prevent impairment (permanent) ☐ Hospitalization ☐ Disability ☐ Other:	

8.	Describe intervention type:	
9.	Relationship of event to intervention:	☐ Unrelated ☐ Possible ☐ Definite
10.	Was the study intervention discontinued due to the event?	☐ Yes ☐ No
11.	What steps were taken to treat the SAE?	
12.	List relevant tests, lab data, history, and pre-existing medical conditions:	
13.	Report type:	☐ Initial ☐ Follow-up ☐ Final

Print Name of Principal Investigator

Signature of Principal Investigator *Date*

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